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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,346

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Eric R Cerny

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HOWREY LLP

C/O IP DOCKETING DEPARTMENT

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FALLS CHURCH, VA 22042

EXAMINER

KRUSE, DAVID H

ART UNIT

PAPER NUMBER

1638

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/541,346

Applicant(s)

CERNY ET AL.

Examiner

David H. Kruse

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2006 and 07 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,11,16,19,21-27 and 33-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21 is/are allowed.
- 6) ☒ Claim(s) 10,11,16,19,22-27,33-36 and 38 is/are rejected.
- 7) ☒ Claim(s) 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/7/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

STATUS OF THE APPLICATION

1. This Office action is in Response to the Amendment and Remarks filed 27 October 2006 and the Response filed 7 June 2007.
2. Those rejections or objections not specifically addressed in this Office action are withdrawn in view of Applicants' amendments.
3. Applicants have perfected the conditions for the Deposit of Biological Materials in the Response filed 27 October 2006 (page 8, 4th paragraph of the Remarks).
4. Applicant's/Assignee's response to the request for information under 37 CFR § 1.105 is acknowledged. The Examiner considers said response as fully responsive to the requirement. Applicant's/Assignee's response has obviated any issue of prior use or on sale under 35 U.S.C. § 102(b).
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

6. Claim 37 is objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 37 is objected for failing to further limit claim 21.

Claim Rejections - 35 USC § 112

7. Claims 16, 22-27, 33 and 34 remain rejected and claims 10, 11, 19, 36 and 38 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written

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description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record set forth in the Office action mailed 31 May 2006. Applicants' arguments filed 27 October 2006 has been fully considered but are not found to be persuasive.

Applicants argue that skilled artisans would readily understand that this locus can be predictably transferred from one genetic background to another by means of out-crossing. Applicants argue that the instant specification reviews this point and discloses that the locus can be inherited in Mendelian fashion. Applicants argue that certain progeny from such a cross would carry the locus in a genetic background different from each parent, and constitute other examples of cotton plants that embody the claim recitations (page 8, 1st paragraph of the Remarks). These arguments are not found to be persuasive because the instantly rejected claims are not directed specifically to an event MON88913 cotton plant, but read broadly on transgenic cotton plants, and method of using, having a glyphosate tolerance transgene located between two 20 base pair sequence (SEQ ID NO: 1 and 2).

See *In re Wallach*, 71 USPQ2d 1939 (CA FC 2004), at 1940: Claims in application directed to isolated DNA molecules encoding proteins that inhibit cytotoxic effects of tumor necrosis factor were properly rejected for failure to satisfy written description requirement of 35 U.S.C. § 112, since applicants claimed nucleic acids encoding protein for which they provided only partial sequence, and without

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approximately 95 percent of amino acid sequence that applicants did not disclose, it cannot be held that DNA molecules claimed in application have been described, since applicants' contention that they were in physical possession of protein does not establish their knowledge of that protein's amino acid sequence or any of its other descriptive properties, even though amino acid sequence is inherent property of protein, and since application does not provide adequate functional description, in that, with only partial amino acid sequence disclosed, chemical structure of nucleic acid molecules that can serve function of encoding protein's amino acid sequence cannot be determined.

While a description of a representative number of species is adequate to represent an entire genus, wherein there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus (see MPEP 2163).

A method is not described if products used in the method are not described. See 64 Fed. Reg. 71427, 71428 (1999), comment No. 4.

8. Claims 16, 22-27, 33 and 34 remain rejected and claims 10, 11, 19, 36 and 38 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for progeny of deposited cotton plant PTA-4854 comprising the cotton event MON 88913, does not reasonably provide enablement for any glyphosate tolerant cotton plant comprising SEQ ID NO: 1 and 2, or methods of using same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record set forth in

the Office action mailed 31 May 2006. Applicants' arguments filed 27 October 2006 has been fully considered but are not found to be persuasive.

Applicants argue that specific vector-cotton junction sequences (e.g. SEQ ID NO: 1 and 2) within progeny plants are easily detected by methods commonly used in the art, such as hybridization and PCR amplification. Applicants argue that these techniques are discussed, for example, in paragraphs 12, 14 and 42 of the specification, hence, cotton plants embodied by the claims are readily identifiable (page 8, 2nd paragraph of the Remarks). These arguments are not found to be persuasive because the instantly rejected claims are not directed specifically to an event MON88913 cotton plant, but read broadly on transgenic cotton plants, and method of using, having a glyphosate tolerance transgene located between two 20 base pair sequence (SEQ ID NO: 1 and 2). Those of skill in the instant art recognize that the introduction and integration of a transgene into a plant genome involves some random events, it is unpredictable where in the genome a transgene will become inserted and "events" are random events and generally cannot be duplicated without undue trial and error experimentation. The transgene of cotton event MON 88913 is the *aroA* gene that encodes an EPSPS enzyme that is tolerant to glyphosate. The instant claims are directed to transgenic cotton plants comprising any inserted transgene that would produce glyphosate tolerance. The specification does not provide guidance on other transgenes useful for producing glyphosate tolerant cotton within the full scope of the instant claims. The specification does not provide guidance on how to make and use cotton plants comprising transgenes for glyphosate tolerance by inserting said

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transgenes into a cotton genome between nucleotides having the sequence of SEQ ID NO: 1 and 2 without undue trial and error experimentation.

Claim Rejections - 35 USC § 103

9. Claims 16, 22-27, 33 and 34 remain rejected and claims 10, 11, 19, 36 and 38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Anderson *et al* (U.S. Patent 6,573,437 published 3 June 2003, and filed 14 September 1993). This rejection is repeated for the reasons of record set forth in the Office action mailed 31 May 2006. Applicants' arguments filed 27 October 2006 has been fully considered but are not found to be persuasive.

Applicants argue that as amended, the claims recite a cotton plant that is glyphosate tolerant by virtue of its comprising an EPSPS-encoding DNA insert at a certain location within the cotton genome. Applicants argue that this location is specifically defined by the sequences SEQ ID NO: 1-4, which, represent the junctions between the DNA, insert and cotton DNA. Anderson does not suggest the use of EPSPS expression vectors at this genomic site in order to derive glyphosate tolerant cotton plants. Applicants argue that given this lack of direction, as well as the level of unpredictability in this art, Applicants argue that the amended claims are not obvious (page 10, 3rd paragraph of the Remarks). These arguments are not found to be persuasive because the instantly rejected claims are not directed specifically to an event MON88913 cotton plant, but read broadly on transgenic cotton plants, and method of using, having a glyphosate tolerance transgene located between two 20 base pair sequence (SEQ ID NO: 1 and 2).

The Examiner notes that SEQ ID NO: 1 and 2 are short primers containing short sequences of cotton genomic and transgene sequences, and SEQ ID NO: 3 and 4 contain sequences of cotton genomic and transgene DNA. The transgene sequences taught in SEQ ID NO: 3 and 4 are from a Fig Mosaic Virus promoter known in the art (SEQ ID NO: 3) and an E9 terminator sequence known in the art (SEQ ID NO: 4).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Claim 21 is allowed.

12. Claim 37 is objected to.

13. Claims 16, 22-27, 33 and 34 remain rejected and claims 10, 11, 19, 36 and 38 are rejected.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The **central FAX number for official correspondence** is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER



David H. Kruse, Ph.D.
25 September 2007

15. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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